REMARKS

Claims 3-13 and 16-19 are pending in the application.

By the foregoing Amendment, claims 3-8, 10, 16, 17, and 19 are amended.

These changes are believed not to introduce new matter, and entry of the Amendment is respectfully requested.

Based on the above Amendment and the following Remarks, Applicant respectfully requests that the Examiner reconsider all outstanding rejections, and withdraw them.

Allowable Subject Matter

Applicant thanks the Examiner for his indication that claims 3, 4, 6, 12, 13, and 16 are allowable.

Rejections under 35 U.S.C. § 103

1. Claims 5, 7-11, and 17-19

On page 2 of the Office Action, claims 5, 7-11, and 17-19 were rejected under section 103(a) as being unpatentable over Itonaga in view of Sacks. To the extent the Examiner may consider this rejection to be applicable to claim 19 as amended, it is respectfully traversed as being based upon a combination of references that does not teach or suggest the claims invention.

As recited in independent claim 19, the present invention is directed to a cuff for measuring physiological parameters of an appendage that comprises:

- a hollow, rigid tube having an inner surface and opposed ends;

- a bladder having an inner surface, an outer surface, and opposed ends, the ends of the bladder being sealed to the ends of the tube to create an enclosed internal volume between the inner surface of the bladder and the inner surface of the tube and an external volume defined by the outer surface of the bladder and surrounded by the internal volume, the bladder having a normal, relaxed state, in which the internal volume is filled with a fluid and a retracted state in which the fluid is evacuated from the internal volume; and
- a plurality of emitters and detectors positioned in the enclosed internal volume for measuring volume or change in volume of the appendage, the number of emitters being governed by the number of physiological parameters being measured other than volume or change in volume, and the number of detectors being governed by the need for spatial differentiation;
- wherein the bladder has a sufficient wall thickness and is made from a material tinted with pigments selected such that the bladder material will absorb the specific wavelengths of light emitted by the emitters to damp light piping but also allow for sufficient transmission of light through the cuff in the appendage.

The Office Action characterizes Itonaga as showing "a blood pressure measuring cuff including an outer rigid casing 12 and a bladder therein 2, with a plurality of emitters and detectors 10 located therein and attached to the inner surface of the bladder." It is respectfully submitted that this characterization of Itonaga's device is in error.

As can be seen from Itonaga's Figure 6(A), the outer surface of the cuff 2 (which corresponds to the inner surface of the claimed bladder) contacts the inner surface of the collar 12. One purpose of the collar 12 is to force the cuff 2 to inflate in the centripetal direction (see column 5, lines 15-20).

Thus, it is impossible for Itonaga's cuff 2 and collar 12 "to create an enclosed internal volume between the inner surface of the bladder [corresponding to the outer surface of Itonaga's cuff 2] and the inner surface of the tube [corresponding to the inner surface of Itonaga's cuff 12]," as required by claim 19. If there were an internal volume "between the inner surface of the bladder [corresponding to the outer surface of Itonaga's cuff 2] and the inner surface of the tube [corresponding to the inner surface of Itonaga's cuff 12]," as required by claim 19, then Itonaga's pressure meter would not function as intended, because the cuff 2 would not be forced to inflate in the centripetal direction.

The Office Action cites Sacks as teaching "an alternate method of forming the bladder, where the bladder is formed by attaching a flexible membrane to the rigid casing." However, there would be no motivation to modify Itonaga's cuff2 and collar 12 to attach the cuff 2 to the rigid casing in accordance with Sacks's purported teaching because as pointed out in the preceding paragraph, the formation of a bladder between Itonaga's cuff 2 and collar 12 would result in a device that would not function as intended.

Further, because Itonaga's cuff 2 and collar 12 cannot "create an enclosed internal volume between the inner surface of the bladder [corresponding to the outer surface of Itonaga's cuff 2] and the inner surface of the tube [corresponding to the inner surface of Itonaga's cuff 12]," as required by claim 19, it also is not possible for Itonaga's pressure meter to have "a plurality of emitters and detectors positioned in the enclosed internal volume," as also required by claim 19.

As set forth in the Declaration of David Bell submitted herewith, Itonaga also does not teach or suggest a plurality of emitters and detectors as recited in claim 19.

The Itonaga patent states at column 4, lines 1-15):

> FIG. 2 shows a finger-type blood pressure monitor which is somewhat different in appearance from that shown in FIG. 1. This monitor has a protruding catch 4a on the end of cover 4 and a corresponding indentation 4b on the interior surface of chamber 3. When cover 4 is closed, catch 4a engages with indentation 4b to insure that the cover will be securely closed. A portion of finger cuff 2 is fixed to the interior of cover 4. When cover 4 is opened, cuff 2 is drawn out of chamber 3 and assumes a cylindrical form suitable for the insertion of a finger. When cover 4 is closed, it pushes cuff 2 down so that it folds in two as it returns to chamber 3. Cuff 2 has three photoelectric sensors 10 to detect the pulse. The light from a luminous element within the cuff is emitted onto the finger, and the light reflected by the finger is detected by photodetector elements.

Itonaga also makes reference to using the detectors or sensors to detect a pulse throughout the application, for example, at column 2, lines 60-64; column 4, line 12; column 4, lines 59-65; and column 6, lines 24-32. Although Itonaga uses the words "pulse detectors or photoelectric pulse sensors," Dr. Bell is of the opinion these elements are ordinary photodiodes, not "pulse sensors," with "pulse" being used to refer to a defined amplitude and frequency.

The true purpose of Itonaga's detectors is described at column 2, lines 34-37 ("With the blood pressure monitor of this invention, the pulse may be detected and pressurization of the cuff begun as soon as the user inserts the finger in the cuff. The user does not need to push a button to start the measurement, so the monitor is easier to operate.") and at column 6, lines 5-10 ("If the cuff is to be pressurized automatically, it should be pressurized a fixed interval after the aforesaid pulse detectors (photoelectric sensors) 10 have detected that a finger has been inserted in the cuff."). In other words, according to Dr. Bell, the "light from a luminous element" described by Itonaga is used as a go, no-go, or more specifically, finger or no-finger, system switch (see column 6, lines 6-9). The luminous element and the photodetectors are not used by Itonaga in measuring blood pressure or any

other physiological parameter. On the contrary, blood pressure values are established in the same way as in conventional blood pressure cuffs, as shown in steps 7 and 8 of the flow chart of Figure 12 and as described at column 7, lines 1-4 ("The cuff is pressurized (Step 7), the maximum and minimum blood pressure values are established (Step 8) and the results are displayed on display 7 (Step 9).").

According to Dr. Bell, if pulse detection and quantification were Itonaga's goal, he would have been much more specific about the luminous element and its location, because if the luminous element is located too far away, a weak pulse will not be detectable. Rather, the location of the luminous element is not described or illustrated, nor is its power source or its window to the finger.

The position of the luminous element is not specified in the drawings and is not exactly located in terms of a datum (relative to the sensors) because it does not have to be so specified or located when used for switch purposes. If it really were used for pulsatile measurements of some kind, its position would have to be exact relative to the detectors, and this location would be immovable in use, which would not meet the design criteria associated with Itonaga's flexible circuit as described at column 2, line 67 - column 3, line 3.

According to Dr. Bell, another indication that pulse detection and quantification were not Itonaga's goal is that the frequency of the luminous element is not specified. The frequency does not have to be specified because in Itonaga's device, the light from the luminous element simply has to detectable when on-like a flashlight through a finger. Light from this element is reflected down the finger surface, across the blackened and shiny surface of the cuff to an "optical" opening occupied by a detector element. Three detectors are provided to ensure that at least one of them "sees" a

change of state produced by light which was bounced along the finger to the clearer portions of the bladder fabric. Non-blackened portions of the cuff increase the "infrared transmission factor" of the cuff fabric adjacent to the detectors (see column 2, lines 60-69 and also column 6, lines 7-9).

Finally, if the luminous element and photodetectors were for measuring physiological parameters, Dr. Bell states that the distance from the source would most likely be exactly specified in terms of a physical separation distance, or "mean free path of photons," or something along a path or line.

For the foregoing reasons, it is Dr. Bell's opinion that when Itonaga refers to sensing a pulse, he really means a change in the signal from some value to another (lighter to darker) light to shadow, etc., or more specifically, the detection of a human finger.

It is also Dr. Bell's opinion that the luminous element must be on the outside, not inside of the cuff, in contrast to the emitters of the present invention as recited in claim 19, which are located in the enclosed internal volume between the bladder and the tube .

According to Dr. Bell, if Itonaga's luminous element is inside the bladder and the bladder cuff surface is as opaque as implied, the bladder must have a window to permit light emission into the finger. No window is specified. On the other hand, the window transparency associated with the sensors is over-specified. Further, no light source is part of the internal PCB that contains the photodiodes. If indeed the luminous element is inside the cuff, there is no apparent path for the light except directly to the photodiodes, which defeats the stated purpose of the windows. One can only assume that the luminous element interfaces with the finger outside the cuff, or along the other layer of the cuff.

2. Claims 17 and 18

On page 3 of the Office Action, claims 17 and 18 were rejected under section 103(a) as being unpatentable over Itonaga in view of Sacks, and further in view of Ukawa. These rejections are believed to be overcome by the amendments to claim 19, for the reasons discussed above with respect to the rejection of claim 19 based on Itonaga and Sacks.

Conclusion

All objections and rejections have been complied with, properly traversed, or rendered moot. Thus, it now appears that the application is in condition for allowance. Should any questions arise, the Examiner is invited to call the undersigned representative so that this case may receive an early Notice of Allowance.

Favorable consideration and allowance are earnestly solicited.

Respectfully submitted,

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Attachment: Declaration Under 37 C.F.R. § 1.132